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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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HM22/1010

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EXAMINER

JARVIS, W

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/599,213

Applicant(s)

WONG ET AL.

Examiner

William R. Jarvis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 19-29, 31, 59 and 60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 30, 32-58, 61 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6, 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. Applicant's election of optically pure (S,S) reboxetine for the treatment of chronic pain in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the election of species requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, claims 1-18, 30, 32-58, 61, and 62 will be examined to the extent that they read on the elected species.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 18, 52-57, 59, and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite since it is not clear what applicant means by "and other somatoform disorders" and "and related spectrum disorders". These claims are indefinite since it is not clear what other disorders applicant intends. Correction (either by deletion of this language or listing of specific disorders (if supported by the disclosure)) is required.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18, 30, 32-58, 61, and 62 (to the extent that they read on the elected species) are rejected under 35 U.S.C. 103(a) as being unpatentable over Reimann et al, Moore et al, Max, Max & Lynch et al, or Max & Kishore-Kumar et al, each in view of applicant's submitted references Dostert et al or Fleishaker et al (Biopharm. Drug Dispos. published January 1999). Reimann and Moore teach that tramadol exerts its analgesic effect largely by inhibiting noradrenaline reuptake. Max states, "Studies in post-herpetic neuralgia and in painful diabetic neuropathy suggest that blockade of norepinephrine reuptake [e.g. by amitriptyline] is the most important action accounting for pain relief..." Max & Lynch et al teach that the selective blocker of norepinephrine reuptake desipramine is effective at reducing pain caused by diabetic neuropathy. Similarly, Max & Kishore-Kumar et al teach that desipramine, amitriptyline, and other related antidepressants exhibit analgesic effect by blocking norepinephrine reuptake. Applicant's elected invention differs in that it specifically requires (S,S)-reboxetine. However, Dostert teaches that (S,S)-reboxetine is the more potent enantiomer. In addition, Fleishaker teaches that the S,S(+) enantiomer of reboxetine is more potent in receptor binding and

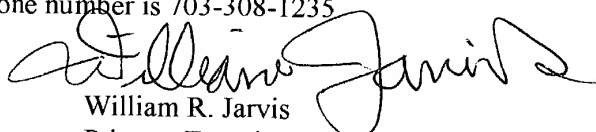
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norepinephrine reuptake inhibition than the corresponding R,R(-) enantiomer; see the second column on page 53. Since the prior art teaches that norepinephrine reuptake inhibition is a biological mechanism for treatment of chronic pain and that the norepinephrine reuptake inhibitor (S,S)-reboxetine is the more potent of the two enantiomers, one skilled in the pharmaceutical arts would have been motivated to treat chronic pain with optically-pure (S,S)-reboxetine. The claimed amounts or dosages are obvious since it is within the skill of the pharmaceutical artisan to determine the amount or dosage of a drug that provides the therapeutic effect most effective for treating the patient's condition while minimizing adverse side effects.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William R. Jarvis whose telephone number is 703-308-4613. The examiner can normally be reached on Monday, Tuesday, Thursday & Friday 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne C. Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


William R. Jarvis
Primary Examiner
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wrj
October 8, 2001